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DATE MAILED: 03/31/2005

| APPLICATION NO. | F | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|---------------------------|--------------|------------|----------------------|------------------------|------------------|--|--|
| 09/905,755 | 5 07/13/2001 | | Jing Cheng | 265/247 | 4001 | | |
| 34263 | 7590 | 03/31/2005 | | EXAMINER | | | |
| O'MELVE | NY & M | EYERS | | BARTON, JEFFREY THOMAS | | | |
| 114 PACIFIC IRVINE, CA | | | | ART UNIT | PAPER NUMBER | | |
| IKVIIVE, CZ | 72010 | | | 1753 | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | <u></u> | | | | | | |
|--|--|--|------|--|--|--|--|
| | Application No. | Applicant(s) | - | | | | |
| | 09/905,755 | CHENG ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | , | | | | |
| | Jeffrey T. Barton | 1753 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with | h the correspondence addr | ess | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 07 Fe | ebruary 2005. | | | | | | |
| · <u> </u> | action is non-final. | | | | | | |
| ,— | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| · | x parte Quayle, 1955 C.D. | 11, 455 O.G. 215. | | | | | |
| Disposition of Claims | | | · | | | | |
| 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 1-16 is/are allowed. 6) Claim(s) 17-19 is/are rejected. 7) Claim(s) 20 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | · | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 1.1) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date J.S. Patent and Trademark Office | Paper No(s | ummary (PTO-413))/Mail Date. <u>20050323</u> . formal Patent Application (PTO- ⁻ | 152) | | | | |

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DETAILED ACTION

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Response to Amendment

1. The amendment filed on 7 February 2005 does not place the application in condition for allowance.

Status of Rejections Pending Since the Office Action of 5 October 2004

- 2. The rejection of claims 1-16 under 35 U.S.C. §112(1) as failing to comply with the enablement requirement is withdrawn due to Applicants' amendment.
- 3. The rejection of claims 1, 2, 4-9, 13, 15, and 16 under 35 U.S.C. §103(a) as unpatentable over Heller et al in view of Markx et al is withdrawn due to Applicants' amendment.
- 4. The rejection of claim 3 under 35 U.S.C. §103(a) as unpatentable over Heller et al in view of Markx et al and Betts et al is withdrawn due to Applicants' amendment.
- 5. The rejection of claims 10-12 under 35 U.S.C. §103(a) as unpatentable over Heller et al in view of Markx et al and Laas et al is withdrawn due to Applicants' amendment.
- 6. The rejection of claim 14 under 35 U.S.C. §103(a) as unpatentable over Heller et al in view of Markx et al and Kambara et al is withdrawn due to Applicants' amendment.
- 7. The rejections of claims 1-20 under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,280,590 in view of various prior art are withdrawn due to Applicants' filing of a terminal disclaimer.

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Terminal Disclaimer

8. The terminal disclaimer filed on 7 February 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,280,590 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

- 9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 10. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (WO 96/07917) in view of Pethig et al.

Regarding claim 17, Heller et al disclose a method of manipulating a biological sample within an apparatus comprising a microfabricated chip (Page 8, lines 4-5) having first and second arrays of electrodes which can each be considered as corresponding to separate reaction areas (e.g. cell sorter matrix 66 and fragment selector 70 of Figure 6; Page 18, line 23 - Page 19, line 5; general matrix discussion on pages 13-17), each electrode being coated with a permeation layer (Page 18, lines 26-29); a "channel-less" flow chamber mounted over the chip (Figure 9 shows cover 136 defining a chamber; Page 28, lines 19-22); and a laser subsystem configured to deliver excitation energy to the electrodes. (Page 25, lines 10-15) This method comprises: introducing a sample into the flow chamber (Page 18, lines 14-22); applying an electric

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field (generally DC) to collect materials at electrodes that are arranged in checkerboard format and to remove undesired materials (e.g. Figures 2-4, matrices discussed on pages 13-17); staining the desired materials (Page 25, lines 12-15); and generating an image of the desired materials using excitation energy from the laser subsystem. (Page 25, lines 16-33)

The cell sorter matrix (66) of Heller et al is broadly disclosed (e.g. Page 18, line 23 - Page 19, line 5), and Heller et al suggest that alternate modes of sorting within their invention are contemplated. (e.g. convective mass transport (Page 29, line 30 - Page 30, line 6) or a superimposed AC field (Page 35, lines 4-15))

Heller et al do not explicitly disclose (a) pumping a separation buffer into the chamber, (b) applying an electric field to provide field maxima at each electrode and minima between them, where desired materials are collected at the maxima and undesired materials at the minima, or (c) washing away undesired materials.

Pethig et al teach detailed methods of dielectrophoresis, which result in trapping of desired materials (viable cells) at field maxima at the electrodes and undesired materials (nonviable cells) at field minima between the electrodes. (e.g. embodiment of Figures 3, 4, and 17; Column 9, line 52 - Column 10, line 37; Column 12, line 47 - Column 13, line 6) Pethig et al also teach selection of a proper buffer for separation of the cells (Column 23, lines 43-49) and washing away undesired materials that had been trapped at the field minima. (Column 13, lines 51-59) Pethig et al also disclose that

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their dielectrophoretic methods are applicable to electrode arrays incorporating varied

shapes and geometries. (Column 3, lines 36-46; Column 23, lines 49-53)

Regarding claim 18, Pethig et al disclose washing the undesired materials away

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while still applying the current to the electrodes. (Column 13, lines 51-60)

It would have been obvious to one having ordinary skill in the art to modify the

method of Heller et al by using dielectrophoretic trapping for selecting the desired cells

within the cell sorter matrix, as taught by Pethig et al, because a skilled artisan would

have recognized that cells are more sensitive to dielectrophoresis than electrophoresis

(i.e. their polarizability is more pronounced than any overall net charge), which would

allow a high degree of control over the sorting process, which was taught in detail by

Pethig et al. (Column 3, line 47 - Column 5, line 17; Column 6, line 65 - Column 7, line

39; several detailed examples also given in the specification) and because Heller et al

suggest such alternate modes of particle sorting and movement in the matrices. (Page

29. line 30 - Page 30, line 6; Page 35, lines 4-15)

Additional disclosure of Heller et al:

Regarding claim 19, Heller et al disclose staining with a fluorescent dye. (Page

25, lines 12-15)

Allowable Subject Matter

Claims 1-16 are allowed.

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12. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

- 13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen discloses dielectrophoretic trapping and sorting using a square array of electrodes.
- 14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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Business Center (EBC) at (866) 217-9197 (toll-free).

JTB

March 23, 2005

nam nguyen

SUPERVISORY PATENT EXAMINER

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